

APPLICANTS: **Gerlach et al.**
U.S.S.N.: **09/898,586**

REMARKS

Claim 19 is pending. Claim 19 has been amended herein to more clearly define the invention. Support for this amendment can be found in the specification as filed, and in originally filed claim 5. No new matter has been added by this amendment.

Election

Applicants note the Examiner's acknowledgement of Applicants' election without traverse and amendment of the pending claim.

Priority

Applicants note with appreciation that the Examiner has acknowledged Applicants' priority claims under 35 USC § 119(e).

Objection in the specification

The Examiner has objected to the specification containing an error in numbering the pages. Applicants file herewith as Appendix A, a replacement page 152, following page 151 in the specification as filed. Thus, this objection is moot and should be withdrawn.

Rejection Under 35 USC § 112, first paragraph

Claim 19 has been rejected under 35 USC § 112, first paragraph, for lack of enablement. The Examiner states that "the specification, while being enabling for a method for determining the presence or amount of a nucleic acid molecule of SEQ ID NO: 23 or encoding the amino acid sequence in SEQ ID NO: 24, does not reasonably provide enablement for a method for determining the presence or amount of any other nucleic acid molecules within the genus recited in the claim." (See Office Action, page 3).

In order to advance prosecution, Applicants have amended claim 19 herein to recite, in part, that "said nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide

APPLICANTS: **Gerlach et al.**
U.S.S.N.: **09/898,586**

comprising the amino acid sequence of SEQ ID NO: 24 or the complement of said nucleic acid sequence.” As acknowledged by the Examiner, this method is enabled by the specification. Thus, Applicants submit that the enablement rejection of claim 19 has been overcome and should be withdrawn.

Claim 19 has also been rejected under 35 USC § 112, first paragraph, for lack of written description. The Examiner states that “claim 19 as written recites a method for determining the presence or amount of a genus of nucleic acid molecules.” (See Office Action, page 5).

As noted above, Applicants have amended claim 19 herein to require that the nucleic acid molecule whose presence or amount thereof in a sample to be determined by the method of claim 19 is either a nucleic acid sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 or the complement of the nucleic acid sequence. As acknowledged by the Examiner, the nucleic acid sequence of SEQ ID NO: 23 and the amino acid sequence of SEQ ID NO: 24 are fully disclosed in the specification as filed (*e.g.*, in Table 49) and the complement of SEQ ID NO: 23 is inherently disclosed in SEQ ID NO: 23. Thus, one skilled in the art would recognize that the Applicants were in possession of the invention of claim 19, and thus, the rejection of claim 19 under 35 USC § 112, first paragraph, has been overcome and should be withdrawn.

Rejection Under 35 USC § 102(e)

Claim 19 has been rejected under 35 USC § 102(e) as anticipated by U.S. Patent No. 5,998,164 (“Li et al.”). The Examiner states that “Li et al. teach a nucleotide sequence encoding at least a portion of polypeptide comprising the amino acid sequence of SEQ ID NO: 24.” (See Office Action, page 8). As indicated in the sequence alignment provided by the Examiner, the sequence disclosed by Li et al. is 69.180% identical and 85.574% similar to a portion of SEQ ID NO: 24, corresponding to amino acids 1-301 of SEQ ID NO: 24. Applicants have amended claim 19 to require that the nucleic acid molecule is either a nucleic acid sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 or the complement of the nucleic acid sequence. Since Li et al. do not disclose the full amino acid sequence of SEQ ID

APPLICANTS: **Gerlach et al.**
U.S.S.N.: **09/898,586**

NO: 24, as required by claim 19 as amended herein, it cannot anticipate this claim. Therefore, this rejection should be withdrawn.

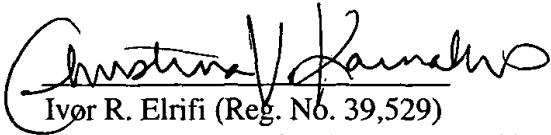
Objection in the claims

The Examiner has objected to claim 19 because it recites an improper Markush group. Applicants have amended claim 19 herein to remove the Markush group. Therefore, this objection is moot and can be withdrawn.

CONCLUSION

Applicants submit that the Examiner's rejections have been overcome based on the enclosed amendments and remarks. Applicants therefore respectfully request that the pending claim be found allowable at this time. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



Ivor R. Elrifi (Reg. No. 39,529)
Christina V. Karnakis (Reg. No. 49,899)
Attorneys for the Applicant
c/o MINTZ, LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

December 17, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

19. (Twice Amended) A method for determining the presence or amount of a nucleic acid molecule in a sample, said nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide comprising [an amino acid sequence selected from the group consisting of:

- i) a mature form of the amino acid sequence of SEQ ID NO: 24;
- ii) a variant of a mature form of the amino acid sequence of SEQ ID NO: 24 wherein any amino acid in the mature form of the chosen sequence is changed to a different amino acid, provided that no more than 15% of the amino acid residues in the sequence of the mature form are so changed;
- iii)] the amino acid sequence of SEQ ID NO: 24, [;
- iv) a variant of the amino acid sequence of SEQ ID NO: 24, in which any amino acid specified in the chosen sequence is changed to a different amino acid, provided that no more than 15% of the amino acid residues in the sequence are so changed;
- v) a nucleic acid fragment encoding at least a portion of a polypeptide comprising the amino acid sequence of SEQ ID NO: 24 or any variant of said polypeptide wherein any amino acid of the chosen sequence is changed to a different amino acid, provided that no more than 10% of the amino acid residues in the sequence are so changed; and]
- vi) or the complement of [any of] said nucleic acid sequences [molecules], said method comprising:
 - (a) providing said sample;
 - (b) introducing said sample to a probe that binds to said nucleic acid molecule; and
 - (c) determining the presence or amount of said probe bound to said nucleic acid molecule,

thereby determining the presence or amount of the nucleic acid molecule in said sample.

THIS PAGE IS INTENTIONALLY LEFT BLANK